

Extractables Testing of Silicone Gel-Filled Devices

10.0 CONCLUSION

Despite the difference in extraction technique, the ten years between sample production and the difference in analytical techniques, the quantitative results of the repeat testing are in good agreement with the previous test results (see Table 6).

- Implant gel contains up to by weight of material extractable by hexane. Of this less than 1% are components of molecular weight less than 1500. Unlike the data previously submitted, the gel extracts contained no detectable components with less than 10 siloxane linkages ($<D_{10}$ or L_6). This is likely due to improvements in the for the polymer used for the gel. The bulk of the hexane extracts of gel appear to be the of peak molecular weight between used in the gel formula³. In addition, the hexane extracts of gel contain a small amount of
- The shell and patch contain two types of extractable components, both siloxanes. There is a small amount (estimated 1/3 of the extracts) of high molecular weight siloxane consistent with the base polymer used in the formulation of the shell material. A larger amount is a series of siloxanes at a level and distribution consistent with that expected from equilibrated siloxane stripped of volatile species^{1,2}.
- Extracts of the shell and patch which have been exposed to gel contain components seen in extracts of each material. The gravimetric results indicate that the gel dissolves into the shell at about of the weight of the shell. The difference in the content of constituents to $Mw < 1500$ between the implant shell and the virgin shell suggests that these lower molecular weight components of the gel are preferentially soluble in the shell.

Table 6: Hexane extractable content of gel-filled implant materials (weight % of material)

		Weight % of oligomers of Mw < 1500			Total wt%	Total % Extractable
		siloxanes	siloxanes	siloxanes		
Hexane extracts of gel	Amendment 19	0.717	0.155	0	0.872	54.2
	This testing	0.46	0.104	0.024	0.588	71.3
Hexane extracts of implant shells	Amendment 19	0.516	0	0.358	0.874	7.2
	this testing	0.346	0.074	0.082	0.502	8.85
		0.383	0.086	0.081	0.550	9.2
Hexane extracts of virgin shells	Amendment 19	0.268	0	1.566	1.834	4.15
	this testing	0.197	0	0.281	0.478	3.74
		0.187	0	0.271	0.458	3.53

11.0 REFERENCES

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- (3) "Safety of Silicone Breast Implants", pg 51, S. Bondurant, V. Ernster & R. Herdman Eds., National Academy Press, Washington D.C., 2000
- (4) "The Analytical Chemistry of Silicones", A.L. Smith, John Wiley and Sons, New York, 1991, p. 151-152
- (5) Ibid, p 460